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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,355	02/14/2002	Hildegard M. Kramer	5190	8887

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GENZYME CORPORATION  
LEGAL DEPARTMENT  
15 PLEASANT ST CONNECTOR  
FRAMINGHAM, MA 01701-9322

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/075,355	KRAMER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 17-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*Handwritten signature/initials*

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### **DETAILED ACTION**

This application claims benefit to provisional application 60/268,559, filed February 14, 2001.

Applicants' amendment filed March 22, 2005, has been received and entered. The specification has been amended. Claims 1 and 4 have been amended. Claims 1-54 are pending.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on July 12, 2004, was acknowledged. No new arguments have been provided and the requirement is still deemed proper and FINAL.

Applicants note that claim 13 appears to have been inadvertently omitted from examination and request that it be considered in the instant action. See Applicants' amendment, page 9. Upon review of the restriction requirement, elected group I included claims 1-13, 15, 16, drawn to a method of making a biocompatible fleece comprising providing solution of a macromer that is hydrophilic, biodegradable and a cross-linking moiety; freezing the solution into the desired shape and cross-linking into a fleece/matrix (classified in class 530, subclass 333). Examiner agrees that claim 13 should have been considered, not withdrawn as indicated in the previous office action.

Claims 1-54 are pending. Claims 14, 17-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the

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reply filed on July 17, 2004. Claims 1-13, 15, 16, drawn to a method of making a biocompatible fleece comprising providing solution of a macromer that is hydrophilic, biodegradable and a cross-linking moiety; freezing the solution into the desired shape and cross-linking into a fleece/matrix, is currently under examination.

As noted previously, the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. In this case, Applicants have elected for examination the process not the product.

However, in the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on

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the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

The disclosure objected to because of the use of the trademark FOCALSEAL-S (page 31, line 13) is withdrawn.

The amendments to the specification has adequately addressed the basis of the objection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 9, 12 and 15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

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The amendment to the claims and Applicants' arguments have been fully considered and found sufficient to address each of the specific basis of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 15, 16 rejected under 35 U.S.C. 102(b) as being anticipate by DeLuca *et al.* (US Patent 4,741,872 issue date May 3, 1988) is withdrawn.

Claims 1-12, 15, 16 rejected under 35 U.S.C. 102(b) as being anticipate by Yannas *et al.* (US Patent 4,955,893) is withdrawn.

The amendment to claim 1, step (d), reciting that the cross-linking is done while the composition is in the frozen state or dried state has differentiated the claimed invention from that disclosed in either DeLuca *et al.* or Yannas *et al.*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca *et al.*, Yannas *et al.*, Allen *et al.* (US Patent 4,962,172) and Solomon *et al.* (US Patent 5,484,604).

The amended claims encompass a process for making fleece comprising the steps of providing a crosslinking polymer in a solution, crosslinking the polymer while it is either in a frozen or dried state (as amended in step 1(d)). Dependent claims have not been amended and set forth adding specific agents to the fleece produced and specific steps of polymerizing and post-processing of the fleece. Again the term fleece is generally described with functionally attributes in the specification (page 6, lines 3-9) and specific cross-linking groups and chemistries are set forth starting at page 8 and specific examples are set forth in Example 1 (as taught for example in US Patent 6,083,524 and 5,410,016).

DeLuca *et al.* teach a process for making biodegradable microspheres by polymerizing macromers including those set forth in the instant specification. Further, DeLuca *et al.* teaches the addition of agents such as drugs to the polymer in addition to washing and freeze-drying steps (see for example Figure 1). Similarly, Yannas *et al.* teach a method of promoting nerve regeneration by providing a biodegradable polymer. The polymer is made by a process of axial

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freezing to produce a structure with orientated pores. Further, Yannas *et al.* teaches that the biological active agent glycosaminoglycan can be added to the polymer that is generated. However, neither teach the specific method step where polymerization is done in a frozen state or in a dried state. As reviewed in the present specification, at the time of filing the art regarding the polymerization of macromolecules was fairly well established. Dependent on the specific agents used, one could activate polymerization by specific means following methodology known in the art. For example, Allen *et al.* (US Patent 4,962,172) teaches that specific polymers can be used and formed in the dried state, for example in claim 11 where drying followings the shaping process. Solomon *et al.* (US Patent 5,484,604) teaches other specific polymers, and a process where the polymer is allowed to dry before cross-linking occurs, for example claim 1 step (A). Further each Allen *et al.* and Solomon *et al.* provide methodology for including the addition of other factors in the resulting polymer. Both DeLuca *et al.* and Yannas *et al.* provide the guidance to make polymers with know structure(s) and orientation(s), and Allen *et al.* and Solomon *et al.* provide details of how such shaping and specific forms can be accomplished by methodology known in the art for any specific polymer used. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to make polymers with defined structures using the methods of DeLuca *et al.*, Yannas *et al.*, Allen *et al.* or Solomon *et al.* with methodology exemplified by Allen *et al.* and Solomon *et al.* for any given set of polymers. One having ordinary skill in the art would have been motivated to use any known methodology for polymerization of a given polymer to provide a final product with a given structure/shape related to its ultimate intended use. There would have been a reasonable expectation of success given the specific results in each of the



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cited references demonstrating the level of skill in the art for making polymers with defined attributes.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

### ***Conclusion***

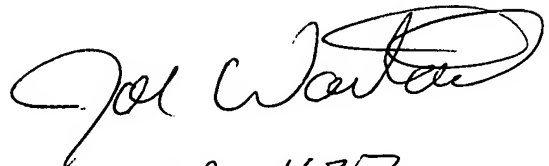
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



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